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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/855,597

05/15/2001

Wai C. Wong

45704-GA/JPW/BJA

9652

7590

08/12/2002

John P. White
Cooper & Dunham LLP
1185 Avenue of the Americas
New York, NY 10036

EXAMINER

COLEMAN, BRENDA LIBBY

ART UNIT

PAPER NUMBER

1624

DATE MAILED: 08/12/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/855,597

Applicant(s)
WONG et al.

Examiner
Brenda Coleman

Art Unit
1624



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on May 24, 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-23, 25, 27-31, 41, 42, 45, and 53-58 is/are pending in the application.
- 4a) Of the above, claim(s) 19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-18, 20-23, 25, 27-31, 41, 42, 45, and 53-58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3, 4 & 5 6) ☐ Other:

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DETAILED ACTION

Claims 13-23, 25, 27-31, 41, 42, 45 and 53-58 are pending in the application.

Election/Restriction

1. Applicant's election with traverse of Group I in Paper No. 7 is acknowledged. The traversal is on the ground(s) that the claims of the Groups I-XXII are not independent. This is not found persuasive because MPEP 2173.05(h) states that "where a Markush expression is applied only to a portion of a chemical compound, the propriety of the grouping is determined by a consideration of the compound as a whole, and does not depend on there being a community of properties in the members of the Markush expression.

Therefore, what should be considered for patentable distinctness is the compound as a whole. Would a whole compound where R_3 is $-Z-(CR_2)_p$ -piperazine be patentably distinct from a whole compound where R_3 is $-Z-(CR_2)_p-R_8$? If a reference for one would not be a reference for the other, then restriction is considered proper. Community of properties is not enough to keep $-Z-(CR_2)_n-W-(CR_2)_n$ -heterocyclic ring, $-Z-(CR_2)_p-R_8$, etc. in the same Markush claim with $-Z-(CR_2)_p$ -piperazine where the Markush expression is applied only to a portion of a chemical compound. It is the compound as a whole $-NHCO-(CH_2)_3$ -4-cyano-4-phenylpiperidin-1-yl vs $-NHCO-(CH_2)_2-CH_3$ vs $-NHCO-(CH_2)_3$ -pyridyl- $(CH_2)_2$ -piperidine, etc., that must be considered for patentable distinctness.

Thus, separate searches in the literature would be required. However, should applicant traverse on the ground that the species are not patentably distinct, applicant should submit

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evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

While it is noted that the term independent is defined under MPEP 802.01 as follows: “independent” (i.e., not dependent) means that there is no disclosed relationship between the two or more subjects disclosed, that is, they are unconnected in design, operation, or effect, for example: (1) species under a genus which species are not usable together as disclosed; or (2) process and apparatus incapable of being used in practicing the process. The only common element among each of the Markush members is the pyrimidine ring which is known in the art.

The requirement is still deemed proper and is therefore made FINAL.

2. Claim 19 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 7.
3. Claims 13-15, 20-23, 25, 27-31, 41, 42 and 45 are rejected as being drawn to an improper Markush group. The recited compounds, while possessing a common utility, differ widely in structure and are not art-recognized equivalents and are thus, independently distinct for the reasons set forth in the restriction requirement. The Markush group represented by the term R_3 has variably different definitions, rendering the claims clearly improper.

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Information Disclosure Statement

4. The information disclosure statement filed May 15, 2001 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. Several of the journal articles were missing from the parent application. The applicants' are requested to provide a copy of those references not initialed so that the record may be completed.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 13-18, 20-23, 25, 27-31, 41, 42 and 45 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amendment to the definition of B where the moiety $-\text{CH}_2\text{OCH}_3$ is not described in the specification for the genus.

Applicant is required to cancel the new matter in the reply to this Office action.

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6. Claims 13-17, 20-23, 25, 27-31, 41, 42 and 45 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amendment to the definition of R_2 where the moiety $-\text{CH}_2\text{X}(\text{CH}_2)_p\text{N}_4$ is not described in the specification for the genus.

Applicant is required to cancel the new matter in the reply to this Office action.

7. Claims 13-17, 20-23, 25, 27-31, 41, 42, 45, 55, 56 and 58 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amendment to the definitions of R_5 and R_7 where R_5 and R_7 each independently may be -H; F; Cl; Br; I; $-\text{CO}_2\text{CH}_3$; -CN; NO_2 ; straight chained or branched $\text{C}_1\text{-C}_7$ alkyl, aminoalkyl, carboxamidoalkyl; straight chained or branched $\text{C}_2\text{-C}_7$ alkenyl or alkynyl, $\text{C}_3\text{-C}_7$ cycloalkyl or cycloalkenyl; wherein the alkyl, aminoalkyl, carboxamidoalkyl, alkenyl, alkynyl, cycloalkyl or cycloalkenyl may be substituted with one or more aryl or heteroaryl, wherein the aryl or heteroaryl may be substituted with F; Cl; Br; I; NO_2 ; -CN; $\text{C}_1\text{-C}_3$ alkyl or carboxamidoalkyl are not described in the specification for the genus.

Applicant is required to cancel the new matter in the reply to this Office action.

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8. Claim 58 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The species of claim 58 is not described in the specification.

Applicant is required to cancel the new matter in the reply to this Office action.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 13-18, 20-23, 25, 27-31, 41, 42, 45 and 53-58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

- a) Claims 13-17, 20-23, 25, 27-31, 41, 42 and 45 are vague and indefinite in that it is not known what is meant by the moiety $-\text{CH}_2\text{X}(\text{CH}_2)_p\text{N}_4$.
- b) Claim 17 recites the limitation " $\text{R}_1-\text{C}(=\text{O})$ " in structure. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

10. Claims 13-15, 20-23, 25 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Atwal et al., U.S. Patent Number 5,202,330. Atwal teaches the compounds of the instant invention where instant R_1 is $C(=O)-O-CH(CH_3)_2$, R_2 is methyl, R_3 is $C(=O)-O-(CH_2)_2-4$ -benzylpiperazine, B is OH and A is 2-chloro-3-nitrophenyl or 2,3-difluorophenyl. See example 34 in column 37 and example 103 in column 89.

11. Claims 13, 20-23, 25 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 62-87574. JP 62-87574 teaches the compounds of the instant invention where instant R_1 is $C(=O)-O-CH_2CH_3$, R_2 is methyl, R_3 is $C(=O)-O-(CH_2)_2$ -piperazine-CH(phenyl) $_2$, B is OH and A is 3-nitrophenyl.

12. Claims 13-17, 20-23, 25, 27-31, 41, 42 and 45 are rejected under 35 U.S.C. 102(e) as being anticipated by Nagarathnam et al., U.S. Patent Number 5,942,517. Nagarathnam teaches the compounds of the instant invention where instant B is OH. See example 1-23.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 13-17, 20-23, 25 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Atwal et al., U.S. Patent No. 5,202,330. The generic structure of Atwal encompasses the instantly claimed compounds (see Formula I, column 3) as claimed herein. Examples 33, 39, 40, 48, 49, 50, 52, etc. differ only in the nature of the Y substituent. Column 3 defines Y as R₁₁ or -O-R₁ where R₁₁ is -A₁-NR₅R₆, etc. and R₁ is -A₁-NR₅R₆, etc. Compounds of the instant invention are generically embraced by Atwal in view of the interchange ability of the Y substituent of the pyrimidine ring system. Thus, one of ordinary skill in the art at the time the invention was made would have been motivated to select for example morpholine as well as other possibilities from the generically disclosed alternatives of the reference and in so doing obtain the instant compounds in view of the equivalency teachings outlined above.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible

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harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. Claims 13-17, 20-23, 25, 27-31, 41, 42 and 45 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 and 19-29 of U.S. Patent No. 5,942,517. Although the conflicting claims are not identical, they are not patentably distinct from each other because the compounds of U.S. '517 embraces the compounds of the instant invention where B is OH.

15. Claims 13-17, 20-23, 25, 27-31, 41, 42 and 45 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 4-11 of U.S. Patent No. 6,248,747. Although the conflicting claims are not identical, they are not

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patentably distinct from each other because the compounds of U.S. '747 embraces the compounds of the instant invention where B is OH.

16. Claims 13-17, 20-23, 25, 27-31, 41, 42 and 45 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 6,268,369. Although the conflicting claims are not identical, they are not patentably distinct from each other because the compounds of U.S. '369 embraces the compounds of the instant invention where B is OH.

17. Claims 13-17, 20-23, 25, 27-31, 41, 42 and 45 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-19 of U.S. Patent No. 6,245,773. Although the conflicting claims are not identical, they are not patentably distinct from each other because the compounds of U.S. '773 embraces the compounds of the instant invention where B is OH.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Coleman whose telephone number is (703) 305-1880. The examiner can normally be reached on Mondays and Tuesdays from 9:00 AM to 3:00 PM and from 5:30 PM to 7:30 PM and on Wednesday thru Friday from 9:00 AM to 6:00 PM.

The fax phone number for this Group is (703) 308-4734 for "unofficial" purposes and the actual number for **OFFICIAL** business is **308-4556**.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

A handwritten signature in cursive script that reads "Brenda Coleman".

Brenda Coleman
Primary Examiner AU 1624
August 9, 2002